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VIA CM/ECF

Peter R. Marksteiner
Clerk of Court
United States Court of Appeals for the Federal Circuit
717 Madison Place, N.W.
Washington, D.C. 20439

Dear Colonel Marksteiner:

Pursuant to Federal Rule of Appellate Procedure 28(j), Appellee writes in response to Appellant's May 30, 2023 letter informing the Court that the Supreme Court of the United States decided *Amgen Inc. v. Sanofi*, No. 21-757.

Appellee agrees that *Amgen* is supplemental authority relevant to this appeal; both Parties, and the District Court in the opinion from which this appeal arises, extensively cited this Court's decision in *Amgen*, which the Supreme Court has now affirmed.

Appellee respectfully disagrees, however, with Appellant's assessment of *Amgen's* impact on this appeal. Appellant has always contended that its patent enables the full scope of the asserted claims because a skilled artisan could create new antibodies within the claimed genera by (i) following Appellant's roadmap (immunizing mice with human Factor IX/IXa, forming hybridomas from the antibody-producing spleen cells of those mice, and testing those antibodies to see if they meet the two claimed functions, i.e., binding Factor IXa and increasing its procoagulant activity), and further (ii) modifying those antibodies into the claimed antibody formats. (*See, e.g.*, Blue Br. at 7–8, 11–17, 23, 33–36, 40, 43–45.) Those are the approaches that the Supreme Court rejected as "little more than two research assignments." Slip Op. at 16. While the Court left open that a "roadmap" might be sufficient on a different record, the very circumstance the Court suggested might suffice—identifying "a quality common to every functional embodiment," *id.* at 17—is precisely what is missing here. Appellant's own experts agree that the patent-in-suit discloses no common structural feature delineating which anti-Factor IX/IXa antibodies will have the two claimed functions. (*See, e.g.*, Appx.53). Appellant's patent claims are not enabled for, among others, the same reasons as in *Amgen*.

Respectfully submitted,

/s/ Eric Alan Stone
Eric Alan Stone

Enclosure:

technology and techniques discussed in the patent for producing and testing antibodies generally, Marasco Rpt. ¶¶ 264–265. But it would not be possible for a person skilled in the art to predict which antibodies would satisfy the claim limitations without trial-and-error testing. *See* Scheiflinger Dep. Tr. at 92:15–93:3; Marasco Dep. Tr. at 205:04–19; Krishnaswamy Dep. Tr. at 168:09–168:19.

11. There is no guidance or direction in the specification of the '590 patent as to how to identify antibodies that satisfy the claim limitations except by using trial and error. *See* Marasco Dep. Tr. at 205:04–19; Krishnaswamy Dep. Tr. at 168:09–168:19; Scheiflinger Dep. Tr. at 92:15–93:3.

12. "The only way to know [what antibodies bind as well as function as needed] is to make antibodies and test them." Krishnaswamy Dep. Tr. at 168:20–169:02; Marasco Dep. Tr. at 218:23–219:04.[10] The '590 patent does not describe what structural or other features of the disclosed antibodies cause them to bind to Factor IX/IXa or to increase the procoagulant activity of Factor IXa. *See* Garcia Rpt. ¶ 130; Scheiflinger Dep. Tr. at 91:23–92:3; 97:23–98:02.

> capabilities by a variety of means, or would have general familiarity with basic concepts in immunology, including basic knowledge of methods for making antibodies and using them as therapeutics. This hypothetical person would be teamed with or have access to other highly skilled individuals with advanced degrees (*e.g.*, Ph.Ds.) in other biological disciplines such as immunology or molecular biology who had several years' experience with methods to produce antibodies that bind to antigens of interest.

Id. ¶ 53; Marasco Rpt. ¶ 264.

[10] "Q. . . . [T]he only way that the patent teaches a person of ordinary skill how to tell whether a given antibody to Factor IX or Factor IXa, in fact, increases the procoagulant activity of Factor IXa is to test that antibody in an assay, correct? A. That's what the patent teaches."